

Press Release

For Immediate Release

Glenmark Pharmaceuticals receives ANDA approval for Sodium Phenylbutyrate Tablets USP, 500 mg

Mumbai, India and Mahwah, New Jersey, November 2, 2022 – Glenmark Pharmaceuticals Limited (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Sodium Phenylbutyrate Tablets USP, 500 mg, the generic version of Buphenyl®¹ Tablets, 500 mg, of Horizon Therapeutics, LLC. Glenmark’s Sodium Phenylbutyrate Tablets USP, 500 mg, will be distributed in the U.S. by Glenmark Pharmaceuticals Inc., USA.

According to IQVIA™ sales data for the 12-month period ending September 2022, the Buphenyl® market² achieved annual sales of approximately \$8.7 million*.

Glenmark’s current portfolio consists of 177 products authorized for distribution in the U.S. marketplace and 46 ANDA’s pending approval with the U.S. FDA. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.

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About Glenmark Pharmaceuticals Ltd

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is an innovation-driven global pharmaceutical company with a presence across Specialty, Generics and OTC businesses. It focuses on the key therapeutic areas of respiratory, dermatology and oncology. The company has 10 world-class manufacturing facilities spread across 4 continents and operations in over 80 countries. Glenmark is ranked among the world’s top 100 biopharmaceutical companies (Top 100 Companies Ranked by Pharmaceutical Sales, 2020, by In Vivo/Scrip 100) and among the world’s top 50 companies in the off-patent sector (Top 50 Generics and Biosimilars Companies ranked by Sales, 2020, by Generics Bulletin/In Vivo). The company was listed on the Dow Jones Sustainability Index (DJSI), one of the world’s most respected and widely accepted sustainability benchmarks, under the category of emerging markets (2021) for the fourth consecutive year. For more information, visit www.glenmarkpharma.com, LinkedIn (Glenmark Pharmaceuticals), Instagram (glenmark_pharma).

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References

¹All brand names and trademarks are the property of their respective owners.

²Market includes brand and all available therapeutic equivalents

*IQVIA™ National Sales Perspectives: Retail & Non-Retail, September 2022